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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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04/12/2006

Vincent J. Colandrea

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EXAMINER

SHTERENGARTS, SAMANTHA L

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

01/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/575,790	Applicant(s) COLANDREA ET AL.	
	Examiner Samantha L. Shterengarts	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 18 and 24-30 is/are pending in the application.
- 4a) Of the above claim(s) 8-10, 12, 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 18 and 28-30 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 11, 26 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12 April 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. The instant application is a national stage entry of PCT/US2004/041887, filed December 13, 2004, which claims priority to U.S. Provisional Application no. 60/530,186, filed December 17, 2003.

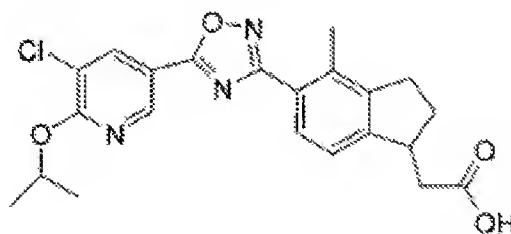
Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on April 12, 2006 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS document was considered. A signed copy of form 1449 is enclosed herewith.

Election/Restrictions

3. Applicant's election without traverse of Group I, Claims 1-11, 18, and 24-30 in the reply filed on October 14, 2008 is acknowledged. Additionally, the election of species of the structure appearing on page 206, claims readable thereon are 1-7, 11, 18, and 28-29 is acknowledged.

4. As per MPEP 803.02, the Examiner will determine whether the entire scope of the claims is patentable. Applicants' elected species of the following compound (page 206):



makes a contribution over the prior art of record. Therefore, according to MPEP 803.02: should the elected species appear allowable, the search of the Markush-type claim will be extended. The search has been extended to compounds represented by Formula A wherein R⁶ is unsubstituted or substituted pyridinyl or phenyl, the ring containing Q, Y, X, T and Z is the same as it is in the

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elected species above, the ring containing U, W, and V is the same fused ring as in the elected species where the R groups are as broadly as represented by claim 1 when the ring is fused, or the ring containing U, W, and V is a phenyl ring, and the R groups are as broadly as represented by claim 1 when the ring is a phenyl, and R⁵ and J are as broad as represented by instant claim 1. It has been determined that the entire scope claimed is not patentable.

Claims 1, 5, 7, 8, 10, 11, 12, 13, 14, 18, 21, 22, and 51, have been examined to the extent to which they are readable on the elected embodiment, example 2 on spec page 32, and the above identified nonelected species. Since art was found on a nonelected species, subject matter not embraced by the elected embodiment or the above identified nonelected species is therefore withdrawn from further consideration.

Status of the Claims

7. Currently, Claims 1-12, 18, and 24-30 are pending in the instant application. Claims 1-7, 11, 18, and 28-29 read on the elected invention. Since the scope of the elected invention has been extended, Examiner will rejoin claims 26-27 and 30 as well. Therefore, Claims 1-7, 11, 18, and 26-30 read on the elected and extended invention and are under consideration in the instant application in so far as they read on the extended search group: compounds represented by Formula A wherein R⁶ is unsubstituted or substituted pyridinyl or phenyl, the ring containing Q, Y, X, T and Z is the same as it is in the elected species above, the ring containing U, W, and V is the same fused ring as in the elected species where the R groups are as broadly as represented by claim 1 when the ring is fused, or the ring containing U, W, and V is a phenyl ring, and the R groups are as broadly as represented by claim 1 when the ring is a phenyl, and R⁵ and J are as broad as represented by instant claim 1. Claims 8-10, 12, and 24-25 are withdrawn from further

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consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention and species.

Claim Objections

8. Claims 6-7, 11, and 26-27 are rejected for containing non-elected subject matter and for depending on a rejected base claim.

Claim Rejections - 35 USC § 112

9. Claims 1-5, 18, and 28-30 are rejected under 35 U.S.C. 112 1st paragraph as failing to comply with the written description requirement.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor has possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention.' Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ('[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'). Thus, an applicant complies with the written description requirement 'by describing the invention, with all its claimed limitations, not that which makes it obvious,' and by using 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.' Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co. the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical

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name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP states that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad genus. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The Guidelines for Examination of Patent Applications Under 35 USC 112, ¶1, "Written Description" Requirement (Federal Register, Vol. 66, No. 4, pg. 1105, column 3), in accordance with MPEP § 2163, specifically state that for each claim drawn to a genus the written description requirement may be satisfied through sufficient description of a representative number of species by a) actual reduction to practice; b) reduction to drawings or structural chemical formulas; c) disclosure of relevant, identifying characteristics (i.e. structure) by functional characteristics coupled with a known or disclosed correlation between function and structure. The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine

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whether applicant has demonstrated possession of the claimed invention (Federal Register, Vol. 66, No. 4, p. 1105, 3rd column, 3rd paragraph). Below is such a comparison.

I. Scope of Claims

Compounds of Formula (A) as found in claim 1.

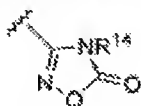
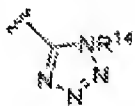
The variable J is claimed broader than what is supported by the disclosure (see section II below).

II. Scope of Disclosure

Reduction to Practice:

Compounds reduced to practice support the following substituents for variable J:

J is selected from the group consisting of: -CO₂H,



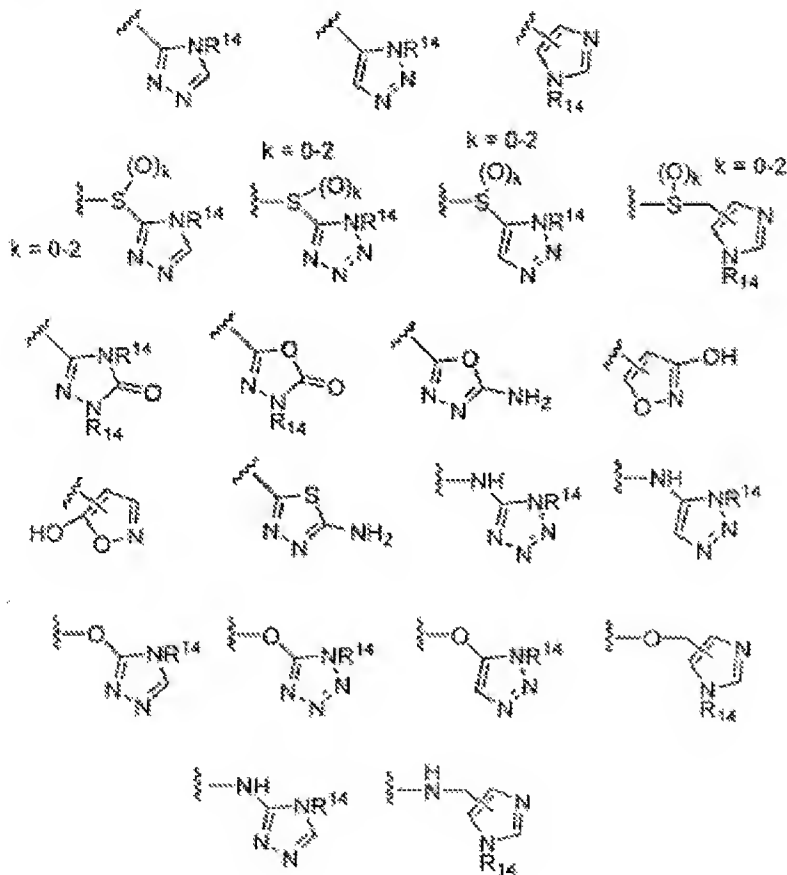
Reduction to Structure or Chemical Formulas

The only disclosure, in addition to the species reduced to practice, is in the form of lists of possible optional substituents for J. This type of disclosure is not viewed to be a representation of any of the species it encompasses. A “laundry list” disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not “reasonably lead” those skilled in the art to any particular species. MPEP 2163.I.A. and *Fujikawa v. Wattanasin*, 93

F. 3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996). Therefore, there is no disclosure of species (e.g. by reduction to structural/chemical formulae) in addition to those reduced to practice.

The embodiments of the instant invention as exemplified in the instant specification do not contain embodiments wherein substituent J is:

J is selected from the group consisting of: $-\text{PO}_3\text{H}_2$, $-\text{PO}_2\text{H}_2$, $-\text{SO}_3\text{H}$, $-\text{CONHSO}_2\text{R}^{13}$, $-\text{PO}(\text{R}^{13})\text{OH}$.



Correlation between Structure and Function:

A correlation between structure and function, for the instantly claimed genus of compounds, is neither known in the art nor disclosed in the specification. Thus, it is

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not understood what specific structural elements are essential for the activity of the instantly claimed compounds for the purposes of acting as immunosuppressive and anti-inflammatory agents.

III. Analysis of Fulfillment of Written Description Requirement:

The structural/activity relationship (SAR) for binding and activity is elucidated upon analysis of IC₅₀ data of multiple compounds with various types of structural modifications. These types of studies provide insight into the structural limitations that are required for activity, i.e., specific structural elements essential for the claimed activity. In the absence of such correlation, it is not possible to determine what structural modifications will allow for the preservation of the desired activity.

In conclusion, (i) substantial structural variation exists in the genus/subgenera embraced by claims 1-5, 18, and 28-30; (ii) disclosure of species supporting genus is limited to compounds reduced to practice, which scope is not commensurate with the scope of genus/subgenera claimed; (iii) common structural attributes of the genus/subgenera, combined with a correlation between structure and function, is neither disclosed in the instant application nor commonly known in the art. Thus, the specification fails to provide adequate written description for the genus of compounds claimed and does not reasonably convey to one skilled in the relevant art that the invention(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

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Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samantha L. Shterengarts/
Examiner, Art Unit 1626

/Kamal A Saeed/
Primary Examiner, Art Unit 1626